In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 6, 2021

CASSANDRA YOST,	*	PUBLISHED
Petitioner,	*	No. 18-288V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Hepatitis B Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA"); Findings of Fact; Onset of Shoulder Pain; Table Injury.
Respondent.	*	

Michael P. Milmoe, Law Offices of Leah Durant, Washington, D.C., for petitioner.
Julia M. Collison, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On February 23, 2018, Cassandra Yost ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") as a result of receiving a hepatitis B vaccination in her left arm on January 13, 2017. Petition (ECF No. 1).

After a review of the record as a whole, including expert reports, medical records, affidavits and briefing by the parties, and for the reasons set forth below, I find by preponderant evidence that the petitioner is entitled to compensation.

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

I. Procedural History

Petitioner filed her petition on February 23, 2018, alleging she sustained a left shoulder injury caused by the hepatitis B vaccine administer to her on January 13, 2017. Petition at Preamble. The case was initially referred to the Special Processing Unit ("SPU"). On January 31, 2019, respondent filed his Rule 4(c) Report, stating that he recommended compensation be denied because petitioner could not establish that she suffered a Table SIRVA. Respondent Report ("Resp. Rept.') at 1, 7 (ECF No. 20). Specifically, respondent stated that the record does not demonstrate that petitioner's symptoms began within 48 hours after vaccination. Resp. Rept. at 7. Respondent stated, "Petitioner did not seek medical care until more than four months after her vaccination at issue." *Id.*

On October 8, 2019, petitioner filed an expert report from Dr. Clifford W. Colwell, Jr.[3] Petitioner's Exhibit ("Pet. Ex.") 13 (ECF No. 29). Petitioner also filed a supplemental affidavit. Pet. Ex. 12 (ECF No. 29). On December 2, 2019, respondent filed a status report stating that he was willing to engage in settlement discussions. Resp. Status Rept. (ECF No. 31). Settlement negotiations between the parties stalled and on April 24, 2020, the case was transferred to my docket. Notice of Reassignment (ECF No. 39).

I held a status conference in this case on May 27, 2020, where I explained that the affidavits filed in this case are consistent with the medical records as to the onset of petitioner's left shoulder injury, which was within 48 hours of vaccination. Scheduling Order (ECF No. 41). Respondent requested an opportunity to file an expert report. *Id.* On June 15, 2020, respondent filed an expert report from Dr. Paul J. Cagle.[4] Resp. Ex. A (ECF No. 42).

On September 4, 2020, I held another status conference in this case, where I reiterated it appeared that petitioner's onset was within 48 hours of receiving the vaccination and that petitioner's diagnosis of bursitis is consistent with the Qualifications and Aids to Interpretations ("QAI") for a Table SIRVA. Scheduling Order at 2 (ECF No. 47). I gave the parties the opportunity to engage in settlement discussions once again. *Id.*

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[3] Dr. Clifford W. Colwell Jr. is an orthopedic surgeon who serves as medical director of the Shiley Center for Orthopaedic Research and Education at Scripps Clinic, located in La Jolla, California. Pet. Ex. 13 at 1. Dr. Colwell received his medical degree from the University of Michigan in 1962 and completed his orthopaedic residency at the Hospital for Special Surgery in New York City. *Id.* He served in the military as an orthopaedic surgeon at Carswell Air Force Base in Ft. Worth, Texas from 1968-1970. *Id.* He is board certified in orthopaedic surgery since 1970. Additionally, he serves as a clinical professor at the Department of Orthopaedics and Rehabilitation at the University of California, San Diego, School of Medicine. *Id.* He also is an adjunct clinical professor at the Department of Basic Science and Clinical Research at The Scripps Research Institute. *Id.* Prior to these positions, Dr. Colwell served as the team physician for the San Diego Padres. *Id.*

[4] Dr. Paul J. Cagle is an orthopaedic surgeon who serves as an Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Siani. Resp. Ex. A at 1. Dr. Cagle received his medical degree from the Loyola University Chicago Stritch School of Medicine. Resp. Ex. B at 2. He did a residency in orthopaedic surgery at the University of Minnesota Academic Health Center and Medical School from 2008-2013. *Id.* He board certified in orthopaedic surgery. *Id.* Prior to working at Mount Siani, Dr. Cagle was an assistant professor and interim chair of the Department of Orthopaedic Surgery at Southern Illinois University School of Medicine. *Id.* He has published numerous articles in peer reviewed journals.

On November 5, 2020, petitioner filed a status report stating that she had forwarded a revised demand to respondent, but that respondent was committed to his previous offer. Status Rept. (ECF No. 50). Petitioner requested that I set a schedule for the parties to file for a ruling on the record for entitlement to move this case into damages. *Id.* at 2.

On February 1, 2021, petitioner filed for a motion for a ruling on the record. Pet. Motion ("Pet. Mot.") (ECF No. 57). Respondent filed a response to petitioner's motion on March 4, 2021. Resp. Response ("Resp. Brief") (ECF No. 58). Petitioner filed a reply on March 19, 2021. Pet. Reply (ECF No. 60).

This matter is now ripe for adjudication.

II. Evidence Submitted

a. Petitioner's Medical Records

On January 13, 2017, petitioner, a 22-year old nursing student at the University of Maryland, received an intramuscular hepatitis b vaccination in her left arm. Pet. Ex. 1 at 1. On May 25, 2017, petitioner had an appointment at Rockville Internal Medicine Group with Dr. Mikhail Shik. Pet. Ex. 5 at 7. At this appointment, petitioner reported that her last physical in June 2016 was normal. *Id.* Petitioner also reported that she had developed left shoulder pain. *Id.* Dr. Shik recorded that petitioner "contributed her symptoms to hepatitis B immunization. She reports that pain started immediately after final booster had been given to her on the left shoulder." *Id.* Petitioner stated that she has pain associated with lifting her arm above 90 degrees in all planes, unable to sleep on her left side and there was a lump at the site of the injection. *Id.* A physical exam of petitioner's left shoulder revealed petitioner had tenderness on palpation on the left shoulder joint, mostly posteriorly and laterally. *Id.* at 8. Additionally, Dr. Shik recorded that petitioner had pain when lifting her arm above 90 degrees in all planes and with resistance, petitioner had pain lifting her arm above 75 degrees in all directions. *Id.* Dr. Shik diagnosed petitioner with "shoulder joint pain," and wrote, "My impression that this pain has not been related to hepatitis B injection. It is most likely due to either prior minor injury or overuse activity. Patient might have mild adhesive bursistis or mild left shoulder joint strain." *Id.* at 9. Dr. Shik referred petitioner to physical therapy and ordered an x-ray. *Id.*

On May 30, 2017, petitioner had an x-ray of her left shoulder, which showed no abnormalities of the bones, joints or soft tissues. Pet. Ex. 4 at 1. Petitioner presented to her first physical therapy appointment on June 5,2017 at the NRH Rehabilitation Network in Rockville, Maryland. Pet. Ex. 2 at 1. Physical therapist, Jessica Lovins, recorded, "History of Present Condition/Mechanism of Injury: Jan 13th [petitioner] had a hep B vaccine injection in her left shoulder and has had pain there ever since. Injection site is swollen and red and raised. Pt is a nursing student at MC[5] and has to use her arms frequently." *Id.* Petitioner reported that she had pain reaching overhead, pain reaching backwards, pain with rolling and changing patients, pain with exercising and pain with sleeping on her left side. *Id.* Upon inspection of petitioner's left shoulder, PT Lovins reported a "pimple-like appearance of injection site that appears to be healing, no radiating erythema. Pt reports recent history of pus coming out of injection site." *Id.*

[5] Montgomery County Nursing School.

Petitioner reported that her pain was a seven at its worst and currently a 2. *Id.* at 9. It was recommended petitioner have physical therapy 2 times a week for a total of 8 visits. *Id.* at 7. On June 24, 2017, at one of the physical therapy appointments, petitioner reported her current pain at a four, but her worst pain still did not exceed a seven. *Id.* at 15.

On June 26, 2017, petitioner had an appointment with Dr. Nicholette Martin at Rockville Internal Medicine Group. Pet. Ex. 5 at 4. Petitioner reported that she has had aching, moderate pain and weakness in her left shoulder for six months and that physical therapy did not help. *Id.* at 5. Dr. Martin recorded that petitioner had hepatitis B vaccine in January 2017 and that petitioner stated it, "Hurt more than any other hep shot. Progressed that night." *Id.* Petitioner also reported that the injection site had one episode of drainage two weeks prior with "popping like a black head." *Id.* A physical exam revealed decreased range of motion of active and passive flexion motion and in active and passive extension. *Id.* Petitioner's left shoulder strength was recorded as a 4-/5 in abduction. *Id.* Dr. Martin assessed petitioner with left shoulder pain and wrote, "? bone bruise from vaccination; meds [as needed]." *Id.* On June 27, 2017, petitioner requested that she be discharged from physical therapy, stating that she felt as if she was not making progress. *Id.* at 16.

On July 28, 2017, petitioner had an annual appointment with Dr. Shik. Pet. Ex. 5 at 1. Dr. Shik stated that petitioner presented for her regular physical and that she needs paperwork filled out because she is returning to school. *Id.* Dr. Shik wrote, "Petitioner has no complaints except for pain in the left shoulder." *Id.* During the physical exam, Dr. Shik observed that petitioner had tenderness on palpation on her left shoulder joint, mostly posteriously and laterally

On August 11, 2017, petitioner had an evaluation of her left shoulder at Shady Grove Orthopedics. Pet. Ex. 3 at 1. In 'History of Present Illness,' Dr. Joseph A. Shrout wrote, "The patient is a 23 year-old female here for evaluation of left shoulder pain. She had a Hepatitis B vaccination on 01/13/17 and has been having increasing pain and swelling." *Id.* He noted that petitioner reported periods of inflammation, pus accumulation, and drainage at the injection site. *Id.* Dr. Shrout performed an exam of the left shoulder, which showed full range of motion but with pain overhead reach, forward flexion and abduction. *Id.* He observed that her rotator cuff strength was normal with resistance, but with pain. *Id.* Dr. Shrout diagnosed petitioner with subacromial bursitis of the left shoulder. *Id.* At this appointment petitioner received a cortisone injection into the subacromial space. *Id.*

Petitioner returned to Dr. Shrout on September 5, 2017 for a follow-up exam of her left shoulder. Pet. Ex. 3 at 3. She reported that the cortisone shot initially gave her significant relief for about two weeks, but the pain returned. *Id.* Petitioner stated that she was taking ibuprofen twice a day to relieve pain. *Id.* At this appointment, she had a positive Neer's test and pain with resistance on the drop arm test. *Id.* Dr. Shrout declined to administer another cortisone injection because it was too close to her last injection. *Id.* He recommended she take Aleve or Advil two to three times a day to relieve pain. *Id.*

On September 19, 2017, petitioner had a follow-up appointment with Dr. Shrout. Pet. Ex. 3 at 5. She reported ongoing pain in her left shoulder and sharp pain when she does not take Aleve. *Id.* Petitioner also reported she was doing exercises at home she learned at physical

therapy. *Id.* Dr. Shrout performed another examination of petitioner's left shoulder, which demonstrated a reduced range of motion on external rotation compared to her right shoulder. *Id.* Dr. Shrout diagnosed petitioner with adhesive capsulitis of the left shoulder and bursitis of the left shoulder. *Id.* He recommended that she continue to do range of motion exercises for her left shoulder at home twice a day daily and take Aleve twice a day. *Id.*

On January 2, 2018, petitioner returned to Shady Grove Orthopaedics and saw Dr. Mark Peterson. Pet. Ex. 3 at 17. Petitioner reported that she had "tremendous pain when trying to move her shoulder at all," and that she had to limit her activities because of her symptoms. *Id.* Dr. Peterson noted that the onset of her left shoulder issues, including pain and stiffness, began "about a year ago (01/13/2017) after receiving a Hepatitis B vaccination." *Id.* Dr. Peterson performed a physical examination where petitioner demonstrated an "external rotation of 70 degrees at her side, abduction to 110 degrees, 50 degrees of external rotation at 90, and internal rotation to L2 (T11 on the right)." *Id.* He diagnosed petitioner with adhesive capsulitis of the left shoulder, and he administered a cortisone injection into her intra-articular space of her left shoulder. *Id.* He also provided her a referral for physical therapy and gave her range of motion exercises to perform at home. *Id.* at 18.

b. Affidavits

1. Petitioner's Affidavits

Petitioner submitted two affidavits in support of her petition. Pet. Ex. 7; Pet. Ex. 12. In her first affidavit, executed on January 4, 2018, petitioner explained that she received her third hepatitis B vaccination on January 13, 2017 at the University of Maryland's Health Center to comply with the vaccination requirements of the Montgomery County Nursing School. Pet. Ex. 7 at ¶ 1. She stated, "This vaccination was different and I felt more pain than previous two hepatitis B vaccinations that I received in the prior months." *Id.* Petitioner explained, "I noticed immediately that it was positioned more toward the back of my upper arm and higher than any of the previous vaccinations." *Id.*

The following morning, her arm was extremely sore, and she could not move it without pain. *Id.* at ¶ 2. She described the injection site where the vaccination was administered as "red and itchy." *Id.* Petitioner took two ibuprofens to alleviate the pain. *Id.* Over the next few weeks, the injection site developed a raised lump and looked red and swollen. *Id.* She stated that the pain in her left shoulder caused significant discomfort during nursing school and everyday activities. *Id.* at ¶ 3. Turning patients, assisting patients to a standing position and retrieving items off high shelves were some of the activities that caused her pain and discomfort. *Id.* She also stated that the pain was so significant that she stopped doing exercises using her left arm. *Id.* At the time of the injection, petitioner had been working as a caregiver for a child with severe cerebral palsy and she could not assist him in or out of his chair without extreme pain in her left shoulder. *Id.*

Petitioner stated that due to her nursing school schedule and part-time job, which included working nights and weekends, she was unable to make a doctor's appointment until the end of her semester. *Id.* at ¶ 4. Additionally, she thought that her shoulder pain would resolve

on its own. *Id.* Petitioner explained that she made an appointment with her primary care physician when her semester ended. *Id.* at ¶ 5. She stated that Dr. Shik observed the red and irritated lump at the injection site and ordered x-rays and to begin physical therapy. *Id.*

Petitioner stated that between May 31 and June 4, 2017, the injection site began to become more raised and irritated. *Id.* at ¶ 6. While in the shower, the lump began to leak pus. *Id.* When petitioner presented for a physical therapy evaluation on June 5, 2017, the petitioner showed the physical therapist the injection site, and the physical therapist commented that the injection site was very irritated. *Id.* Between June 16 and June 24, 2017 petitioner attended physical therapy at NRH Montrose, but stated that she did not feel any relief from physical therapy and often experienced more pain after the sessions. *Id.* at ¶ 8.

Petitioner stated that at her physical examination for school on July 28, 2017, she informed Dr. Shik that her left arm had not improved and the lump at the injection site was still, "raised, red, irritated and was accompanied by occasional drainage." *Id.* at ¶ 10. After Dr. Shik recommended seeing an orthopedist, petitioner went to Shady Grove Orthopedics. *Id.* at ¶ 11.

Petitioner explained that Dr. Shrout gave her a cortisone shot, which provided relief within the hour. *Id.* at ¶ 11. However, the effects of the shot wore off within 10 days. *Id.* She stated that when she saw Dr. Shrout for the third time, on September 17, 2017, she was experiencing persistent significant shoulder pain and an irritated injection site. *Id.* at ¶ 12. At this appointment, Dr. Shrout explained to petitioner that she had "frozen shoulder," and it would eventually resolve on its own. *Id.*

Petitioner stated that she returned to Shady Grove Orthopedics in January 2018, as instructed by Dr. Shrout if her pain persisted. *Id.* at ¶ 13. Petitioner reported that the pain in her shoulder would wake her up several times at night. *Id.* She stated that "she was in tears while my shoulder was being manipulated at the appointment." *Id.* At this appointment, Dr. Peterson, who administered a second cortisone shot and referred petitioner back to physical therapy. *Id.*

Petitioner stated that her left shoulder has been in constant pain since receiving the hepatitis B injection on January 3, 2017. *Id.* at ¶ 14. She explained that the pain has severely impacted her nursing school duties, tasks at work and overall health. *Id.*

Petitioner's second affidavit, executed on September 17, 2019, described the photographs that petitioner submitted as Exhibit 11. Petitioner stated that the location on her arm where the injection was given would cycle through phases of being a "dark spot of hyperpigmentation, to a raised red lump, to a draining sore, back to a darkened area all to repeat itself in a few weeks." Pet. Ex. 12 at ¶ 2. She explained that the cycle stopped only after the draining sore eventually expelled a small, hard, black body from the injection site." *Id.* Petitioner stated that she decided to take pictures of the vaccine location due to the peculiarity of the area where the needle entered her arm and because the site was not healing. *Id.* at ¶ 3.

2. Affidavit of Catherine Shaer, M.D.

Petitioner submitted an affidavit of Dr. Catherine Shaer, executed on July 29, 2019, who had formerly served as a medical officer at the Department of Health and Human Services, Division of Vaccine Injury Compensation. Pet. Ex. 10. Dr. Shaer stated that she had met the petitioner several years ago through a mutual friend. *Id.* at ¶ 1. Dr. Shaer explained that she would see the petitioner every few weeks to months. *Id.*

Dr. Shaer stated that the mutual friend had told her that petitioner had been experiencing significant pain in her shoulder since receiving a vaccine required by her nursing school program in the early spring of 2017. *Id.* at ¶ 2. Dr. Shaer explained to her friend that it was possible the pain was directly related to the receipt of the vaccine and they discussed SIRVA. *Id.* Dr. Shaer stated that she ran into the petitioner about a week or so later and they also discussed the condition of petitioner's shoulder. *Id.* Dr. Shaer explained that she did not recall the conversation "word for word," but, "very clearly remember the substance and some of the specific details." *Id.*

Dr. Shaer stated that petitioner told her that "she had experienced unusually severe left shoulder pain immediately upon receipt of a vaccine in January, and that it had gotten worse over a period of time, and was still quite painful." *Id.* at ¶ 3. Dr. Shaer stated that she had "jumped to the conclusion that it was not a big deal in terms of negatively affecting her life and said something about her being lucky that she was able to sleep well….and how problematic that would be with her school work and work schedule." *Id.* Dr. Shaer stated that petitioner responded that she was actually having difficulty sleeping because she could not lie on her left side and the pain had interrupted her sleep for months. *Id.* Dr. Shaer also stated that petitioner informed her that she could not carry her purse on her left shoulder and the pain was exaggerated with some movements to the point where it was interfering with her ability to perform some duties in nursing school, such as turning and lifting patients. *Id.*

Dr. Shaer explained that petitioner described how a small draining lesion appeared at the site of the vaccination that drained and cleared up only to recur. *Id.* at ¶ 3. The petitioner showed Dr. Shaer the location of the lesion and Dr. Shaer stated, "the first thing that struck me was the fact that the spot was way too high and posterior indicating to me that the shot had clearly been given in the wrong location. I did not see a lesion but I did see a circular area of what I felt was post inflammatory hyperpigmentation (a dark spot) about ¼ in diameter exactly where she was pointing." *Id.* Dr. Shaer advised petitioner to seek a doctor for a full evaluation, as "she could very well have SIRVA." *Id.* Petitioner responded that she was busy with school and work, did not have a physician and had been hoping the pain would resolve on its own. *Id.* Dr. Shaer stated, "I distinctly remember thinking that I knew where she was coming from because, as a pediatrician, I had seen many young adults with the same approach to a medical issue, even a persistent one." *Id.* Dr. Shaer again recommended petitioner find a physician and also recommended that she take pictures of the lesion if it reappears. *Id.*

Dr. Shaer stated that she spoke to petitioner a few weeks later and the petitioner reported that she had seen a doctor and been referred to physical therapy. *Id.* at ¶ 4. When Dr. Shaer saw the petitioner later, petitioner reported that physical therapy was very painful and petitioner felt

that the physical therapy was causing her shoulder pain to be worse. *Id.* Dr. Shaer explained to petitioner that she could change physical therapists if the session continued to cause severe pain. *Id.* Dr. Shaer later learned that petitioner had discontinued formal therapy but decided to do at home exercises. *Id.*

Dr. Shaer explained that she also had the opportunity to examine the lesion which reappeared on petitioner's shoulder. *Id.* at ¶ 5. Dr. Shaer stated that she saw "a small abscess, a little smaller than a quarter inch in diameter, right in the middle of the area of hyperpigmentation. It was pointing (coming to a head), but not draining." *Id.* at ¶ 5. Dr. Shaer stated, "Here was something that was like an 'X marks the spot' of the inoculation, months after the vaccine had been administered and that spot was nowhere near where an intramuscular vaccine should be properly administered in the arm." *Id.* at ¶ 5. It was after seeing the abscess, Dr. Shaer mentioned to petitioner that "she might want to consider filing a vaccine injury claim." *Id.*

Dr. Shaer stated that while she worked at HHS, there were two other occasions where she discussed possible vaccine injury claims in her private life. *Id.* at ¶ 7. While attending a party, an acquaintance explained that she had been diagnosed with neuromyelitis optica and her ophthalmologist attributed it to the receipt of the influenza vaccine. *Id.* Dr. Shaer explained program requirements and suggested that the woman discuss the situation with her ophthalmologist. *Id.* Dr. Shaer also described a time when her sister, a registered nurse, inquired about a friend who had developed polymyalgia rheumatica after receiving an influenza vaccination. *Id.* Dr. Shaer stated that she informed her sister that she did not believe there was any scientific evidence that the influenza vaccine could cause polymyalgia rheumatica, and her sister's friend could always file a claim in the program. *Id.*

Dr. Shaer stated that since retirement from HHS as a medical examiner, she discussed the Vaccine program with some of her husband's colleagues in September of 2018 during a trip to Arizona. *Id.* at ¶ 8. She explained that one of the individuals at the lunch described how she received a flu shot that was described as "too high on the arm," and had suffered with significant shoulder pain and problems with certain movements. *Id.* Dr. Shaer explained to the group that she places her opposite hand over her shoulder of the arm which the vaccine is to be administered to avoid having the shot too high on the arm. *Id.*

c. Photographs of injection site

Petitioner submitted five photographs of the injection site on her left arm. Pet. Ex. 11. The first photo, dated, "May 17, 2017," shows petitioner's left arm and a red-brownish spot, located above her axillary fold and more towards the back of her arm than the front. Pet. Ex. 11 at 1. The second photo, dated May 31, 2017, again shows petitioner's left arm and the same spot as identified in the first picture, but now with a red and raised bump with a dark center. *Id.* at 2. The third photograph, dated June 1, 2017, shows the petitioner's left upper arm and she is holding a quarter next to the injection site, which appears red and raised. *Id.* at 3. Again, the red spot is more posterior and is above her axillary fold. *Id.* The fourth photograph is dated June 1, 2017 and it shows petitioner's upper left arm and shoulder without the quarter. *Id.* at 4. There appears a red, raised bump located towards the back of petitioner's left arm and above the

axillary fold. The final photograph, dated June 4, 2017, shows the petitioner's upper left arm and shoulder. *Id.* at 5. This photograph is taken from behind the petitioner, which shows a red, raised bump that now appears to be purulent. *Id.* at 5. Importantly, on June 5, 2017, petitioner had her first physical therapy evaluation and the physical therapist, Jessica Lovins, also inspected the injection site and described it as, "Pimple-like appearance of injection site that appears to be healing, no radiating erythema. Patient reports recent history of pus coming out of injection site." Pet. Ex. 2 at 1. Further, when petitioner presented to Dr. Joseph Shrout for an evaluation, he noted a "small raised area at the previous injection site…" Pet. Ex. 3 at 1.

d. Petitioner's expert report of Dr. Clifford W. Colwell

Petitioner submitted an expert report from Dr. Clifford W. Colwell, Jr., an orthopedic surgeon. Pet. Ex. 13. Dr. Colwell stated that he reviewed petitioners exhibits and it was his opinion that petitioner "meets the defined definitions of SIRVA as outlined by the Vaccine Injury Compensation Program ("VICP')." *Id.* at 1.

Dr. Colwell explained that there was no indication that petitioner had any previous history of left shoulder pain, inflammation or dysfunction of the affected shoulder prior to her receiving the hepatitis B vaccine on January 13, 2017. *Id.* He also stated that petitioner's reduced range of motion "was limited to the shoulder in which the vaccine was given," and "no other condition or abnormality is present that would explain petitioner's symptoms." *Id.* at 2.

Regarding onset of petitioner's pain, Dr. Colwell stated, "…looking at the record as whole, it is my opinion that the onset of [petitioner's] pain began within 48 hours of receiving the vaccination." *id.* at 1. Dr. Colwell acknowledged that petitioner did not seek medical attention for her shoulder until May 2017, more than four months after the receipt of the hepatitis B vaccine, but that at her initial appointment, petitioner "consistently reported that her pain started when the vaccine was administered." *Id.*

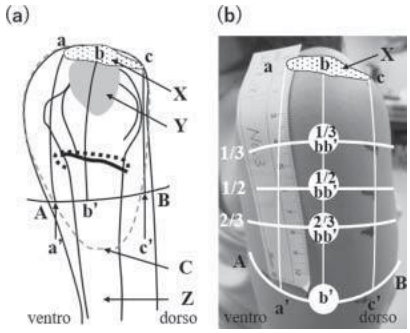
Dr. Colwell stated that, "Orthopaedic surgeons often rely on facts supplied by friends, family members, and associates of our patients. I see no reason to doubt the information presented here." *Id.* at 1-2. He also noted that, "…it is reasonable to me as a medical professional that an otherwise healthy, young, full-time nursing student, who was also working part-time, would wait until the end of her semester's studies to seek medical attention." *Id.* Dr. Colwell also explained that the information in the three affidavits are consistent with the petitioner's medical records and "when…read in conjunction with the medical records, I conclude that the onset of [petitioner's] shoulder pain was within the 48-hour period required by the regulation." *Id.* at 2.

Dr. Colwell also stated that he had reviewed the petitioner's pictures of her left shoulder contained in Exhibit 11. *Id.* at 2. He noted that location of the lesion is "more lateral and posterior than the location in which an intramuscular injection should be given in the upper arm." *Id.* He concluded by stating, "…in my opinion as a board certified Orthopaedic surgeon, [petitioner] meets the four regulations required by the Vaccine Injury Table for demonstrating a SIRVA injury…" *Id.*

e. Respondent's expert report of Dr. Paul Cagle

Respondent submitted an expert report by Dr. Paul Cagle, an orthopaedic surgeon. Resp. Ex. A. Dr. Cagle stated that the medical records support a case of shoulder bursitis. *Id.* at 4. He stated that he agreed with petitioner's physician, Dr. Shik that petitioner's shoulder injury was associated with an "overuse injury," and that it was his opinion that petitioner's injury is not correlated with the vaccination and were not caused by the vaccination. *Id.*

After a review of petitioner's medical records, Dr. Cagle stated that the course taken by Dr. Shrout and Dr. Peterson is consistent with a diagnosis of subacromial bursitis. *Id.* at 3. He stated that bursitis is a common diagnosis for SIRVA events and "the injury mechanism published for SIRVA is an injection placed "too high" in the shoulder (at the top of the shoulder)." *Id.* He stated that "too high" typically means 3 cm or less from the acromion, as the bursa extends only that far down the arm. *Id.* Dr. Cagle cited to article by Nakajima et al., which reviewed four commonly used injection sites for intramuscular injections in the deltoid muscle, and found that even these common sites "….have the potential to cause injury to the subdeltoid/subacromial bursa and/or anterior branch of the axillary nerve with the arm in the anatomical position." Resp. Ex. K at 1.[6] Dr. Cagle stated that the Nakajima article posits that the safest site for intramuscular injections was, "the intersection between the anteroposterior axillary line, and the perpendicular line from the mid-acromion." *Id.* The authors stated that, "The safest site for IM injections was identified as b'…" and it is identified in the image below:



Resp. Ex. K at 2. The authors note that image (a) is the anatomical structure of the left shoulder and image (b) is an image of the anatomical structures on a living body. *Id.* The authors noted that Y on figure (a) is the subdeltoid/subacromial bursa. *Id.* The authors stated that, "…the location of b' was distant from the axillary nerve, posterior circumflex humeral artery ("PCHA") and subacromial/subdeltoid bursa. Therefore, b' was identified as the safest site for IM injections in this study." *Id.* at 4. The authors of Nakajima et al. stated that another study recommended that, "a safer intramuscular injection site was 7.4 cm below the mid-acromion in both sexes due to the course of the axillary nerve and position of the subacromial/subdeltoid bursa." *Id.* They noted that in their study, "…the distances from the mid-acromion lateral border to b' were….8.5 to 11.0 cm in females." *Id.*

[6] Nakajima, Y. et al., *Establishing a new appropriate intramuscular injection site in the deltoid muscle*, 13 Human Vaccines & Immunotherapeutics 2123-2129 (2017). [Resp. Ex. K].

Dr. Cagle argued that the Center for Disease Control ("CDC") recommended that an intramuscular injection "safe zone," is located above what the authors of Nakajima et al. recommended for a safe injection site. Resp. Ex. A at 3; Resp. Ex. L. Dr. Cagle stated that based on the CDC recommended injection site, the region just superior to the axilla (arm pit) is also safe. Resp. Ex. L. Dr. Cagle stated that, "The images for this case clearly show the injection site to be below the level of the CDC recommended area and clearly more than 3 cm from the acromion." *Id.* He concluded that petitioner's injection site, based on the photographic evidence, is "well in line with the axillary fold and located in the region described by Nakajima et al. as ideal." *Id.* at 3.

Dr. Cagle also stated that petitioner's expert, Dr. Colwell did not provide a mechanism of action or a discussion of how "such a distal skin lesion cold correlate with an injury associated with a superior structure (the bursa)." *Id.* at 3. Dr. Cagle stated, "Subsequent data localized this diagnosis to the subacromial bursa and skin images demonstrated an injection site far distal to the anatomic boundaries of the bursa," thus he concluded that, "the findings are not correlated with the vaccination and were not caused by the vaccination." *Id.* at 4.

III. Factual Issues

a. Applicable Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). "Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

Respondent does not dispute that petitioner received the hepatitis B vaccination at issue in her left deltoid on January 13, 2017. The primary disagreement in this case involves the onset of petitioner's left shoulder pain. Pet. Mot. at 9-13; Resp. Brief at 9-11.

b. Petitioner's arguments

Petitioner argues that the onset of her pain was within 48 hours of receiving the vaccination. Pet. Mot. at 10. She argues that she consistently attributes the pain in her shoulder to the vaccination once she established care. *Id.* Petitioner notes that at multiple doctor's appointments on May 25, 2017 and beyond, she reported that her left shoulder pain began when she received the hepatitis B vaccination on January 13, 2017. *Id.*

Petitioner states that the two sworn affidavits she submitted both attribute the onset of her pain to the day of the vaccination. *Id.* at 11; Pet. Exs. 7 & 12. Additionally, the affidavit by Catherine Shaer, M.D., a former medical examiner at HHS, provides corroborating evidence consistent with petitioner's medical records. *Id.* at 12. Petitioner explains that she is similarly situated as the petitioner was in *Tenneson v. Sec'y of Health & Human Servs.,* where the former Chief Special Master found that onset of the petitioner's shoulder pain began within 48 hours by relying on affidavits submitted by and for petitioner that were consistent with the medical records. *Id.* at 11 (citing to *Tenneson v. Sec'y of Health & Human Servs.,* No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Dec. 18, 2018; *aff'd* 142 Fed. Cl. 329 (2019). In her case, petitioner argues, her two affidavits and the affidavit of Dr. Shaer are completely consistent with the medical records and the records work in tandem to provide preponderant evidence of onset within 48 hours of her January 13, 2017 vaccination. *Id.* at 12.

Petitioner also argues that she had a credible explanation for seeking a delay in treatment. *Id.* at 12. She states that the delay in seeking treatment should not be interpreted as a sign that her injury was not severe, but instead she was extremely busy with nursing school and working on both the weekends and evenings. *Id.* at 12. In her reply brief, petitioner argues that, "a gap in treatment for which there are no medical records is not the same as actual medical records that do or do not address a particular issue." Pet. Reply at 3. She states that the "contemporaneously created medical records petitioner has presented, repeatedly and consistently note petitioner's January 13, 2017, injection as the onset of her injury and pain. These records were created by medical professionals who examined petitioner, assessed her symptoms, spoke with her and diagnosed her left shoulder issues," and consistent with *Curcuras,* whichare presumed to be accurate and warrant consideration as trustworthy evidence. *Id.* at 3 (citing *Curcuras v. Sec'y of Health & Human Servs.,* 933 F.2d 1524, 1528 (Fed. Cir. 1993) (holding that medical records, in general, warrant consideration as trustworthy evidence.). This is particularly true when the records are consistent in terms of their description of the onset, location and nature of her injury as they are in this case.

c. Respondent's arguments

Respondent argues that petitioner has not established "the requisite facts to establish entitlement to compensation for a Table SIRVA." Resp. Brief at 9. Specifically, he argues that the record does not demonstrate that petitioner's symptoms began within 48 hours after vaccination. *Id.* at 10. Respondent states that petitioner waited *four months* after vaccination to seek medical care. *Id.* at 10 (original emphasis). According to respondent, "Such a lengthy absence of any contemporaneous medical records is fatal to petitioner's claim," and the lack of

treatment and reporting symptoms is valid evidence in and of itself that petitioner's symptoms did not begin within the requisite time period. *Id.* at 10.

Additionally, according to respondent, the petitioner's medical records attribute the onset of petitioner's pain to overuse. *Id.* at 11. Respondent argues that medical records created closer in time to the vaccination can be afforded greater weight and the most contemporaneous record in this case, notes that petitioner had been "exercising vigorously prior to," the onset of petitioner's left shoulder pain. *Id.* at 11. Respondent states that petitioner's treating physician determined her left shoulder pain was more likely attributable to overuse than to the vaccination in January 2017. *Id.*

Further, respondent argues that petitioner's affidavits on their own are insufficient to establish onset within 48 hours. *Id.* at 11. Respondent states that Section 13(a)(1) of the Vaccine Act is clear that petitioner's claims alone cannot support a finding of entitlement to compensation, unsubstantiated by medical record or medical opinion. *Id.* at 11-12.

Finally, respondent argues that petitioner has not provided sufficient credible evidence to support her claim that her January 2017 hepatitis B vaccine was the cause of her shoulder bursitis. Resp. Brief at 15.

IV. Entitlement

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 300aa-13(a)(1)(A), 11(c)(1); *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In this case, petitioner alleges that she suffered a Table Injury. Thus, petitioner must show that she suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown by the government that the injury was caused by some other factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); §300aa-14(a); § 300aa-13(a)(1)(B).

SIRVA is an injury listed on the Vaccine Injury Table ("Table"). The QAI explains that, "SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.)." 42 C.F.R. 100.3(c)(10). The SIRVA criteria under the Qualifications and Aids to Interpretation are as follows:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs,

> symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id. The hepatitis B vaccine is a covered vaccine and the Table specifies that for a Table SIRVA, onset must occur within 48 hours. *Id.* at §100.3(a)(VIII).

a. No history of pain, inflammation or dysfunction of the affected shoulder.

Nothing in the medical records suggests that petitioner ever had any manifestation of pain or dysfunction in her left shoulder prior to the vaccination at issue. Respondent has made no argument on this criterion. Resp. Rept. 7-10. Additionally, petitioner's expert, Dr. Colwell, who reviewed petitioner's records stated that there was no indication that petitioner had any previous history of left shoulder pain, inflammation or dysfunction of the affected shoulder prior to receiving the hepatitis B vaccine on January 13, 2017. Pet. Ex. 13 at 1.

b. Pain occurs within the specified timeframe (48 hours).

Based on the record as a whole, I find there is preponderant evidence that the onset of petitioner's shoulder pain was within 48 hours of her January 13, 2017 hepatitis B vaccination.

Respondent's main argument regarding this criterion is that petitioner did not seek treatment until four months after receiving the hepatitis B vaccination. Resp. Rept. at 7; Resp. Brief at 10. Respondent states that, "the lack of treatment and reporting symptoms is valid evidence in and of itself. Such a lengthy absence of any contemporaneous medical record is fatal to petitioner's claim." Resp. Brief at 10. Respondent argues that petitioner's statements in her affidavits and statements made to medical professionals for treatment are not sufficient to establish onset within 48 hours. Respondent states, "Accordingly, any statements by petitioner are insufficient *on their own* to establish a reasonable basis for a petition because the special master is precluded from ruling for petitioner on that evidence." *Id.* at 12. Notably, respondent disregards the statements of Dr. Cathine Shaer, stating that her affidavit does not adequately support petitioner's assertions of immediate onset because the discussion Dr. Shaer had with petitioner occurred in Spring of 2017, not January 2017. Resp. Brief at 11, n.9.

Respondent's argument that petitioner's lack of treatment and reporting the symptoms immediately is fatal to her claim is unpersuasive. First, the Vaccine Act provides that a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." §300aa-13(b)(2). Second, prior decisions by other Special Masters have found that postponing or delaying treatment for limited number of months is not *per se* dispositive of whether onset of shoulder pain occurred within the specified time period for a SIRVA. *Lang v. Sec'y of Health & Human Servs.*, NO. 17-995V, 2020 WL 7873272 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); *See also e.g. Forman-Franco v. Sec'y of Health & Human Servs.,* No. 15-1479, 2018 WL 1835203 (Fed.

Cl. Spec. Mstr. Feb. 21, 20-18); and *Tenneson v. Sec'y of Health & Human Servs.,* No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019).

In *Desai v. Secretary of Health & Human Services*, I found that the petitioner had established onset within 48 hours even though she had delayed treatment for her shoulder injury by three months. No. 14-811V, 2020 WL 4919777 (Fed. Cl. Spec. Mstr. July 30, 2020). Much like in this case, petitioner in *Desai*, provided a credible reason for delaying treatment for three months. Further, like the petitioner in *Desai*¸ the petitioner consistently related the onset of her shoulder pain to the vaccination she received on January 13, 2017. Even though petitioner's first medical appointment following the hepatitis B vaccination was on May 25, 2017, approximately four months after the vaccination, the record created at that visit is presumed to be trustworthy as medical record contemporaneous to her treatment, having been created to facilitate diagnosis and care for her shoulder pain. *See e.g. Cooper v. Sec'y of Health & Human Servs.,* No. 16-1378V, 2018 WL 1835179, at *6 (Fed. Cl. Spec. Mstr. Jan. 18, 2018); *see also Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010). At the May 25, 2017, petitioner reported that she developed left shoulder pain and Dr. Martin recorded, "[petitioner] attributed her symptoms to hepatitis B immunization." Pet. Ex. 5 at 7. At later appointments, petitioner consistently attributed her left shoulder pain to her January 13, 2017 vaccination. *See* Pet. Ex. 2 at 1 ("Jan 13 patient had a hep B vaccine injection in her left shoulder and has had pain there ever since"); Pet. Ex. 3 at 1 ("[petitioner] had a Hepatitis B vaccination on 1/13/2017 and has been having increasing pain and swelling"); and Pet. Ex. 5 at 4 ("[patient] had hep B vaccine Jan 2017. Hurt more than any other hep shot. Progressed that night"). There were no inconsistencies in petitioner's reports to her medical providers.

Additionally, respondent's argument that petitioner is relying solely on her own statements to support a finding of entitlement to compensation is equally unpersuasive for multiple reasons. First, when denying the respondent's motion for review, Judge Kaplan observed in *Tenneson v. Secretary of Health & Human Services,* that the prohibition in Section 13(a)(1) is against finding a cause-and-effect relationship between a vaccine and an injury without any substantiation by medical evidence or opinion, "but does not speak to the circumstances under which particular subsidiary facts relevant to causation (such as, for example, the fact of a vaccination or the onset of date of any injury) may be established by preponderant evidence on the basis of lay testimony, so long as the overall finding of causation is sustained by medical records or medical opinion. 142 Fed. Cl. 329 at 339 (2019).

Second, the petitioner's medical records were not created by the petitioner, but contained information supplied by the petitioner to health professionals to facilitate diagnosis and treatment of her left shoulder injury, therefore, these records are considered trustworthy. *See Cucuras*, 993 F.2d at 1528. Petitioner's affidavits are consistent with the medical records in attributing the onset of her left shoulder pain to the hepatitis B vaccine she received on January 13, 2017 and she provided a reasonable explanation as to why she delayed treatment. As a nursing student and working part-time nights and weekends, petitioner had to wait until the end of her school

semester to seek treatment. Her first medical appointment, on May 25, 2017, coincides with the ending of the 2017 spring semester academic calendar.[7]

Finally, petitioner is not relying solely on her statements, but submitted an affidavit of a witness, Dr. Catherine Shaer, who provided a detailed affidavit about her interactions with petitioner. *See* Pet. Ex. 10. Dr. Shaer's affidavit reiterates that petitioner associated the onset of her pain to the vaccination which she received in January 2017. Pet. Ex. 10 at ¶ 3. Dr. Shaer was also able to recount specific details about her encounter with the petitioner the first time she saw her in the Spring of 2017, including how petitioner was unable to carry her purse on her left shoulder and the pain was interfering with petitioner's ability to perform tasks at nursing school such as turning and lifting patients. *Id.* Respondent argues that Dr. Shaer's affidavit does not adequately support onset within 48 hours because she did not see the petitioner within 48 hours of the vaccination, but instead, in the spring of 2017. Resp. Brief at 11, n. 9. I agree with petitioner that respondent mistakenly criticizes the affidavit of Dr. Shaer. Even if though the conversation occurred in the spring of 2017, it does not diminish the trustworthiness of the statements relayed to Dr. Shaer by petitioner regarding onset. Importantly, the statements made by Dr. Shaer in her affidavits were consistent with those provided by the petitioner and with the medical records created by the petitioner's treating physicians. There is nothing in the record that is inconsistent with petitioner's onset occurring within 48 hours of vaccination, and as such, petitioner has established onset of pain within 48 hours of receiving her January 13, 2017 hepatitis B vaccination.

c. Pain and reduced range of motion confined to the shoulder

There is nothing in the record to suggest that petitioner was seeking treatment for her right shoulder or any other medical condition other than her left shoulder injury, nor did respondent raise any argument regarding this criterion. Additionally, petitioner's expert, Dr. Colwell stated that, "[Petitioner's] reduced range of motion was limited to the shoulder in which the vaccine was given." Pet. Ex. 13 at 2. As such, petitioner has demonstrated by preponderant evidence that her pain and reduced range of motion was confined to her left shoulder in which her intramuscular hepatitis B vaccine was administered on January 13, 2017.

d. No other condition or abnormality explains petitioner's symptoms

Finally, respondent argues that petitioner "has not established that she more likely than not received a vaccination in a location that could cause bursitis." Resp. Brief at 12. Respondent's expert, Dr. Cagle, agrees that petitioner has a confirmed diagnosis of subacromial bursitis. Resp. Ex. A at 3. Then Dr. Cagle states, "Bursitis is a common diagnosis for SIRVA events, and the injury/mechanism published for SIRVA is an injection placed "Too High" in the shoulder." *Id.* at 4. But Dr. Cagle opines that petitioner's shot was given at a safe location, and thus could not have been the cause of petitioner's bursitis. *Id.* at 3-4. Dr. Cagle states, "The images for this case clearly show the injection site to be below the level of the CDC recommended area and clearly more than 3 cm from the acromion…..the injection is well in line with axillary fold, and in fact it is located in the region described by Nakajimma et al. as ideal."

[7] 2016-2017 Academic Calendar, Division of Academic Affairs, Office of the Provost, University of Maryland, https://svp.umd.edu/archived-calendars/2016-17 (accessed on Friday, April 30, 2021).

Id. at 3. Dr. Cagle also states, "I agree with Dr. Shik's original diagnosis of shoulder injury associated with an overuse injury of vigorous exercise." *Id.* at 4.

In her reply brief, petitioner reiterates that she is alleging a Table Injury and cites to the QAI for SIRVA which provides, "…symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle *into and around* the underlying bursal of the shoulder resulting in an inflammatory reaction." Pet. Reply at 5 (original emphasis) (citing 42 C.F.R. § 100.3(a)(XIV)(B). Petitioner states that she "need not prove that vaccine antigen actually entered the bursa," and the "into and around" language of the QAI is more than satisfied." *Id.*

I agree with petitioner. First, Dr. Cagle oversimplifies the mechanism for SIRVA as described in the medical literature. The article by Atanasoff et al. states that, "The proposed mechanism of injury is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Resp. Ex. C at 1.[8] Atanasoff et al. reviewed 13 claims for shoulder pain post-vaccination and found that 46% of patients expressed concern that their vaccine was administered "too high." *Id.* at 2. Instead, they opined that, "If…a vaccine is inadvertently injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues, present as a result of earlier naturally occurring infection or vaccination, may lead to a more prolonged inflammatory response." *Id.* at 3. Atanasoff et al. cited to the Bodor and Montalvo article, which found that the "subdeltoid bursa extended from 3.0 to 6.0 cm beyond the lateral border of the acromion and that it lies between .8 to 1.6 cm below the skin surface." *Id.* at 2; Resp. Ex. F.[9] Bodor and Montalvo hypothesized in their article that the vaccine was injected into the subdeltoid bursa, which is contiguous with the subacromial bursa, which led to subacromial bursitis, bicipital tendonitis and inflammation of the shoulder capsule. Resp. Ex. F at 3. The measurements of the subdeltoid bursa by Bodor and Montalvo are consistent with the measurements in the Nakajima et al article, which found that the mean distance from the mid-acromion to the subacromial/subdeltoid bursa was 4.0 cm in females. Resp. Ex. K at 5. Further, the Nakajima article asserts that the safe injection site was 8.5 to 11.0 cm from the mid-acromion lateral border in females to avoid the posterior circumflex humeral artery and the subacromial/subdeltoid bursa. Resp. Ex. C at 4.

Dr. Cagle asserts that petitioner's images show that the injection was given in a safe location, by being "clearly more than 3cm from the acromion….and well in line with the axillary fold…in fact it is located in the region by Nakajima et al. as ideal." Resp. Ex. A at 3. However, his assertion is inconsistent with the medical literature. Both the Nakajima et al. article and the Bodor article indicate that the subdeltoid/subacromial bursa can extend beyond 3cm below the lateral border of the mid-acromion. Furthermore, observation of the photos of the injection site appear to show, as Dr. Colwell noted, that the injection was given posteriorly and laterally to where an intramuscular injection should be given and the photos do appear to show that the injection site was above the axillary line. Additionally, Dr. Shaer, petitioner's witness, also observed the injection site and stated that "the spot was way too high and posterior indicating to

[8] Atanasoff, S. et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049-8052 (2010). [Resp. Ex. C].

[9] Bodor, M. & Montalvo, E., *Vaccination-related shoulder dysfunction*, 25 Vaccine 585-587 (2007). [Resp. Ex. F].

me that the shot had clearly been given in the wrong location." *See* Pet. Ex. 10 at ¶ 2. Therefore, given the location of petitioner's injection scar, it is most likely that the injection was given in a location in or around the underlying bursa of the shoulder resulting in an inflammatory reaction.

Second, petitioner is correct that the QAI for SIRVA does not require petitioner to articulate a mechanism for injury. As Special Master Horner observed in *Lang v. Sec'y of Health & Human Servs.*, "it would be incompatible with the very idea of the Vaccine Injury Table to hold petitioner to a burden of proving causation to establish a Table injury." No. 17-995, 2020 WL 7873272, at n.9 (Fed. Cl. Spec. Mstr. Dec. 11, 2020). Importantly, to demonstrate a Table Injury, a petitioner need only to show that he or she suffered an injury contemplated by the Vaccine Injury Table that corresponds with the vaccination in question, the onset of the injury took place within the timeframe specified in the Table and meets the criteria of the injuries outlined in the QAI, the injury is presumed to have been caused by the vaccination, unless the respondent can affirmatively show that the injury was caused by some factor other than the vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i); § 300aa-13(a)(1)(B); and § 300aa-14(a). Further, the QAI for SIRVA provides the mechanism for the injury. The QAI provides, "SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur *as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction."* 42 CFR Part 100.3(c)(10) (emphasis added). Thus, respondent's argument that petitioner's expert, Dr. Colwell, did not specifically "weigh-in" on whether the location of the injection scar is consistent with the bursitis diagnosis is superfluous.

Finally, Dr. Cagle's opinion that petitioner's diagnosis of bursitis is the result of overuse and a history of vigorous exercise is unsupported in the record. In fact, the Atanasoff et al. article, filed by respondent, considers this exact type of diagnosis, stating, "Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection substance into the subacromial bursa or the area around the rotator cuff tendon." Resp. Ex. C at 3. The authors continue, observing that, "…this type of phenomenon is not due to a specific vaccine but results from injection of a vaccine antigen to which a person has previously been sensitized as a result of previous naturally occurring infection or past vaccination." *Id.* In this case, petitioner explained to her treating physician that she developed left shoulder pain in January and that her pain "started immediately after final booster [had] been given to her on the left shoulder." Pet. Ex. 5 at 11. Further, this was petitioner's third hepatitis b vaccination. *See* Pet. Ex. 6 at 7, 9-10. The previous two hepatitis b vaccination were also administered in petitioner's left deltoid indicating that she had been previously sensitized to the antigen in question. *Id.* at 7, 9. Thus, the sudden onset of petitioner's left shoulder pain following her third hepatitis B vaccination is consistent with the theory proposed in the Atanasoff et al. article filed by respondent.

e. Factor unrelated

Pursuant to the Vaccine Act, once petitioner has met her *prima facie* burden of demonstrating a Table Injury, respondent may still prove the condition is "due to factors unrelated to the administration of the vaccine described in the petition." § 300aa-13(a)(1)(B). In this case, apart from the diagnostic consideration of overuse due to vigorous exercise discussed above, respondent has not raised any issue as to any factor unrelated to vaccination. The argument as to an overuse injury was unpersuasive in light of the consistent attribution of the pain to the vaccine administration in a manner consistent with pain arising from vaccine administration.

V. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA following her January 13, 2017 hepatitis B vaccination as alleged. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master